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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,276	12/03/2003	Wasimul Haque	12695.13USD2	1586
23552	7590	07/06/2005	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/729,276	Applicant(s) HAQUE ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-26-05</u> . | 6) <input type="checkbox"/> Other: _____ |

8-0-0

Applicants' Amendment filed April 26, 2005 is acknowledged. Claims 1-6 remain under consideration.

An Information disclosure Statement filed April 26, 2005 is further acknowledged and has been reviewed. The Information Disclosure Statement filed March 5, 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance of each document. The documents referred to therein have not been considered. Applicants' representative may contact the Examiner directly concerning this matter.

Applicants have an obligation to call to the attention of the Patent Office the most pertinent prior art in a proper fashion. Burying one reference in one hundred other IDS references amounts to citing nothing. *PENN YAN BOATS, INC. v. SEA LARK BOATS, INC.* 175 USPQ 260 (DC Sfla 1972). *GOLDEN VALLEY MICROWAVE FOODS, INC. v. WEAVER POPCORN CO., INC.* 24 USPQ2d 1801 (U.S. Dist. N. Dist.).

Applicants are requested to provide a complete list of co-pending and related applications when responding to this Office Action.

The Abstract of the disclosure is objected to because the present Abstract recites compounds that are not present in the instant claims. Correction is required. See MPEP § 608.01(b).

In the last Office Action claims 1-6 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-18 and 21-28 of copending Application No. 10/411552. Claims 1-6 were provisionally rejected under the judicially created doctrine of obviousness-type double

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patenting as being unpatentable over claims 1 and 20 of copending Application No. 10/639955.

Applicants have elected to hold these issues in abeyance. The rejections of record under the judicially created doctrine of obviousness-type double patenting are maintained.

Claims 1-6 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the treatment of cerebral ischemia, cerebral hemorrhage, ischemic stroke or hemorrhagic stroke comprising administering pyridoxal-5'-phosphate, pyridoxal, pyridoxine or pyridoxamine. The specification provides support for the treatment of cerebral ischemia in a rat model comprising administering pyridoxal-5'-phosphate. It was asserted the instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation.

Applicants argue the Background section of the specification outlines the main general characteristics of the claimed diseases, as does the state of the art at the time of filing. Applicants urge cerebral ischemia, cerebral hemorrhage, ischemic stroke and hemorrhagic stroke are all cerebrovascular diseases resulting from a similar pathology. A reference to the parent application that has issued as U.S. Patent 6, 861,439, is noted.

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Applicants' arguments are not persuasive. Cerebral ischemia is a decrease in the blood supply to the brain or cerebrum; cerebral hemorrhage is an escape or excessive loss of blood from blood vessels of the brain; ischemic stroke is a sudden loss of brain function caused by a decrease in the blood supply to the brain or cerebrum; hemorrhagic stroke is a sudden loss of brain function caused by an escape or excessive loss of blood from blood vessels of the brain. The pathology is often not similar. Each particular ischemic or hemorrhagic neurologic disease or disorder has its own specific characteristics and etiology.

The parent application is limited to treatment of cerebral ischemia or ischemic stroke, for which support for anti-ischemic effects is provided.

The rejection of record under 35 U.S.C. 112, first paragraph, is maintained because the specification fails to provide support for the breadth of the claimed subject matter. Applicants have failed to provide guidance as to which among the claimed compounds would be preferred for treatment of cerebral hemorrhage or hemorrhagic stroke.

Claims 1-6 were rejected under 35 U.S.C. 103(a) in the last Office Action as being unpatentable over Skochii et al., *Likars'ka sprava / Ministerstvo okhorony zdorov'ia Ukrainy*, (Sept.-Dec., 1994) (9-12) 109-11 (abstract). It was asserted the Ukrainian document teaches the administration of pyridoxal phosphate in the treatment of cerebral stroke.

Applicants have provided an English translation of the reference and argue Skochii discloses a combination therapy comprising four antioxidants of which one is

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pyridoxal phosphate. Applicants urge it is a very weak antioxidant, and with reference to the Woodside reference, argue it does not increase the resistance of low density lipoprotein to oxidation. Applicants argue Woodside teaches the B-group vitamins do not have an antioxidant effect.

An antioxidant effect is not herein claimed. Skochii teaches combination therapy, of which pyridoxal phosphate is a part, lowered the blood content of LPO products significantly. Skochii's assay determined the effect of the combination therapy in a patient population who suffered either ischemic or hemorrhagic stroke only through the sole parameter of a change in pol (peroxidation of lipid). Following an ischemic or hemorrhagic stroke a substantial increase of pol was noted. Ten days after treatment pol levels appreciably decreased. Skochii urges the importance of pol and suggests a treatment for stroke. The Woodside reference is directed to cardiovascular, not cerebrovascular conditions.

The rejection under 35 U.S.C. 103(a) is maintained for the reasons of record.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

January 23, 2005